

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 5/23/2017-6/2/2017* FEI NUMBER 3012053582
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen J. Rhoades, Director of Quality

FIRM NAME QuVa Pharma, Inc.	STREET ADDRESS 1075 W Park One Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY Sugar Land, TX 77478-2576	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

On 05/23/2017, we observed three out of (b) (4) of that day's production technicians resting their elbows on the front areas of multiple laminar airflow hoods while producing sterile drug products.

This behavior was observed during the production of:

1. Ropivacaine HCL PF 0.2%, 2mg/ml, Lot #10003990, NS 200 mL in 250 mL, Cassette (400 mg), in clean room (b) (4) inside laminar airflow hood #3, serial (b) (4) produced by technician one.
2. Fentanyl Citrate, PF 2mcg/mL/ Bupivacaine HCL PF 0.125% in 0.9% Sodium Chloride, 250 mL, Lot #10003982, in clean room (b) (4) inside laminar airflow hood #3, serial (b) (4) produced by technician two.
3. Magnesium Sulfate PF 2g added to 5% Dextrose, 50 mL, Lot #10004066, in clean room (b) (4) inside biosafety cabinet #2, serial (b) (4) produced by technician three.

***DATES OF INSPECTION**

5/23/2017(Tue), 5/24/2017(Wed), 5/25/2017(Thu), 5/26/2017(Fri), 5/30/2017(Tue), 5/31/2017(Wed), 6/01/2017(Thu), 6/02/2017(Fri)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Jason R Caballero, Investigator
Shatina R Alridge, Investigator

X Jason R Caballero
Jason R Caballero
Investigator
Signed by: Jason R. Caballero -S

6/2/2017

DATE ISSUED

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